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FACSIMILE TRANSMISSION COVER SHEET

DATE:

September 23, 2004

TO:

Examiner: Rei Tsang Shiao

Group Art Unit 1626 Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

RE:

U.S. Patent Application No. 10/721,204

For: NOVEL FUSED INDAZOLES AND INDOLES AND THEIR USE FOR THE TREATMENT OF GLAUCOMA

Our Ref: 1966 (3010-003-01)

FROM:

Luke A. Kilyk, Esq. 7

FAC. TEL. NO.:

1-703-872-9306

NUMBER OF PAGES (INCLUDING THIS COVER SHEET): 5

Items Attached: Response to Restriction Requirement -- 4 pages

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| Donald S. Prater | Dayles Sinter | |
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| In re Application of: MAY et al. | Examiner: Rei Tsang Shiao |
|----------------------------------|---------------------------|
| Application No.: 10/721,204 | Group Art Unit: 1626 |
| Filed: November 25, 2003 | Confirmation No.: 5525 |
| Docket No.: 1966 (3010-003-01) | Customer No.: 33432 |
| | |

For: Novel Fused Indazoles and Indoles and Their Use for the Treatment of

GLAUCOMA

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

September 23, 2004

Sir:

This Response is in response to the Office Action dated August 23, 2004, which set forth a restriction requirement. The Examiner has set a one-month period for response, thus making the response due on or before September 23, 2004.

In the Office Action, the Examiner sets forth an eleven-way restriction requirement and requested that applicants elect one group for examination purposes.

In response, the Applicants elect with traverse the subject matter of Group I drawn to compounds of formula (I) wherein X and Y are N, Z is C, A is a 6-membered ring containing 6 carbon atoms, R² and R³ do not form a heterocycle and R¹, R⁴, R⁵ and R⁶ are as defined in claim 1.

The Examiner further required an election of a single compound or species within

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Response to Restriction Requirement U.S. Patent Application No. 10/721,204

the elected group. In response, Applicants elect, with traverse, the compound of Example 1, which is 2-(2-aminopropyl)-2,6,7,8-tetrahydro-benzo[cd]indazol-4-ol.

The restriction requirement is traversed on the grounds that there is no serious burden on the Examiner to examine all of the claims of the application. Under M.P.E.P. §803, if a search and examination of an entire application can be made without a serious burden on the Examiner, the Examiner must examine it on its merits, even if it includes claims to distinct and separate inventions.

Contrary to the Examiner's statements, each of the compounds set forth in the claims clearly have a related structure as set forth in formula I which is set forth in claim 1. This general structure would permit the Examiner to easily search the entire scope of each claim. The Examiner has provided no detailed reason why a detailed search would be burdensome especially since the Examiner has only provided two different classes or sub-classes for purposes of achieving the search of the entire application. Furthermore, if one would accept the Examiner's restriction requirement, this would mean the filing of eleven separate patent applications which would be incredibly unfair to the applicants and quite unusual considering that related technology has not been restricted the same way. In fact, applicants can refer to a number of patents where the entire scope of the subject matter having similar chemistry was completely examined by the United States Patent and Trademark Office. The Examiner's attention is directed, for instance, to U.S. Patent No. 6,696,476. Therefore, there is clear evidence that previous Examiners did not find a search of the entire subject matter burdensome. Therefore, it would appear that the present Examiner should not have any burden as well. The applicants further reserve the right to petition this matter to the Group Director in order to have the restriction requirement withdrawn at the appropriate time. 09/23/2004 13:20 5404281721 KILYK BOWERSOX PLLC PAGE 04

Response to Restriction Requirement U.S. Patent Application No. 10/721,204

Therefore, applicants will not cancel or amend any claim that includes non-elected subject matter at this time.

Furthermore, at page 6 of the Restriction Requirement, the Examiner asserts that in accordance with several legal decisions, restriction of a Markush group is proper where the compounds within the group either do not share a common utility or do not share a substantial structural feature disclosed as being essential to that utility. It is respectfully noted that the Examiner has not fully or properly addressed the standards recited in the cases relied upon by the Examiner. First, it is clear, the Examiner does not disagree that each of the compounds set forth in formula I of claim 1 clearly share a common utility, namely the treatment of glaucoma. In addition, as clearly shown by the structure set forth in formula I, each of the formulas share a substantial structural feature which provides or contributes to the utility of the present application. This is the whole reason that structural formula I is provided and set forth in claim 1. Accordingly, based on the Examiner's own cited decisions, this restriction requirement is improper and should be removed and all of the subject matter in the claims should be examined at this time.

With respect to the species requirement, the applicants again believe that the election of a species is not required and clearly, the Examiner can examine all of the species at this time. At a minimum, upon the allowance of the elected species, the Examiner, according to MPEP rules, will proceed with examining other species within the elected invention.

Thus, it is respectfully submitted that there would be no serious burden on the part of the Examiner to examine all of the claims at this time. Accordingly, the Applicants respectfully request that the Examiner reconsider the restriction requirement and group the claims so that they are all examined at this time. 09/23/2004 13:20 5404281721 KILYK BOWERSOX PLLC PAGE 05

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At the very least, the Applicants request that all of the subject matter drawn to compounds of formula (I) wherein X and Y are N and Z is C (that is, all of the indazole compounds) be also examined at the same time. This subject matter encompasses Groups I and II and compounds in the catch-all Group IV wherein X and Y are N and Z is C. It is respectfully submitted that these compounds share a common utility (treatment of glaucoma) and a substantial structural feature (an indazole core with an attached ethylamine derivative) that is relevant to that utility. It is respectfully submitted that the selections for the six-membered ring A and the selections for R¹, R², R³, R⁴, R⁵ and R⁶ are sufficiently few in number or are so closely related that it would not be a serious burden on the Examiner to examine all of these compounds at the same time. Accordingly, in the alternative, the Applicants respectfully request that the restriction be redrawn so that all of the indazole compounds are searched together.

If there are any other fees due in connection with the filing of this Preliminary Amendment, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such extension is requested and should also be charged to our Deposit Account.

Respectfully submitted,

Luke A. Kilyk

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Atty. Docket No. 1966 (3010-003-01) KILYK & BOWERSOX, P.L.L.C.

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